

comprehensive, systemic operational plan to ensure the health and safety of participants.

(7) Quality assessment and performance improvement program.

(b) *Participant advisory committee.* (1) A PACE organization must establish a participant advisory committee to provide advice to the governing body on matters of concern to participants. Participants and representatives of participants must constitute a majority of the membership of this committee.

(2) The participant advisory committee must provide the liaison to the governing body with meeting minutes that include participant issues.

(c) *Participant representation on the governing body.* (1) A PACE organization must ensure participant representation on issues related to participant care. This shall be achieved by having a participant representative on the governing body.

(2) The participant representative is a liaison of the participant advisory committee to the PACE organization governing body.

(3) *Duty of the participant representative.* The participant representative must present issues from the participant advisory committee to the governing body.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006]

**§ 460.64 Personnel qualifications for staff with direct participant contact.**

(a) *General qualification requirements.* Each member of the PACE organization's staff that has direct participant contact, (employee or contractor) must meet the following conditions:

(1) Be legally authorized (for example, currently licensed, registered or certified if applicable) to practice in the State in which he or she performs the function or action;

(2) Only act within the scope of his or her authority to practice;

(3) Have 1 year of experience with a frail or elderly population;

(4) Meet a standardized set of competencies for the specific position description established by the PACE organization and approved by CMS before working independently.

(5) Be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact.

(b) *Federally-defined qualifications for physician.* In addition to the qualification specified in paragraph (a) of this section, a physician must meet the qualifications and conditions in § 410.20 of this chapter.

[71 FR 71334, Dec. 8, 2006]

**§ 460.66 Training.**

(a) The PACE organization must provide training to maintain and improve the skills and knowledge of each staff member with respect to the individual's specific duties that results in his or her continued ability to demonstrate the skills necessary for the performance of the position.

(b) The PACE organization must develop a training program for each personal care attendant to establish the individual's competency in furnishing personal care services and specialized skills associated with specific care needs of individual participants.

(c) Personal care attendants must exhibit competency before performing personal care services independently.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006]

**§ 460.68 Program integrity.**

(a) *Persons with criminal convictions.* A PACE organization must not employ individuals or contract with organizations or individuals—

(1) Who have been excluded from participation in the Medicare or Medicaid programs;

(2) Who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under title XX of the Act; or

(3) In any capacity where an individual's contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug, or alcohol abuse.

(b) *Direct or indirect interest in contracts.* The PACE organization shall identify members of its governing body or any immediate family member having a direct or indirect interest in any

contract that supplies any administrative or care-related service or materials to the PACE organization.

(1) PACE organizations must develop policies and procedures for handling any direct or indirect conflict of interest by a member of the governing body or by the member's immediate family.

(2) In the event of a direct or indirect conflict of interest by a member of the PACE organization's governing body or his or her immediate family member, the board member must—

(i) Fully disclose the exact nature of the conflict to the board of directors and have the disclosure documented; and

(ii) Recuse himself or herself from discussing, negotiating, or voting on any issue or contract that could result in an inappropriate conflict.

(c) *Disclosure and recusal requirements.* A PACE organization must have a formal process in place to gather information related to paragraphs (a) and (b) of this section and must be able to respond in writing to a request for information from CMS within a reasonable amount of time.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002; 71 FR 71335, Dec. 8, 2006]

#### § 460.70 Contracted services.

(a) *General rule.* The PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization except for emergency services as described in § 460.100.

(b) *Contract requirements.* A contract between a PACE organization and a contractor must meet the following requirements:

(1) The PACE organization must contract only with an entity that meets all applicable Federal and State requirements, including, but not limited to, the following:

(i) An institutional contractor, such as a hospital or skilled nursing facility, must meet Medicare or Medicaid participation requirements.

(ii) A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services it furnishes.

(iii) A contractor must comply with the requirements of this part with respect to service delivery, participant rights, and quality assessment and performance improvement activities.

(2) A contractor must be accessible to participants, located either within or near the PACE organization's service area.

(3) A PACE organization must designate an official liaison to coordinate activities between contractors and the organization.

(c) *List of contractors.* A current list of contractors must be on file at the PACE center and a copy must be provided to anyone upon request.

(d) *Content of contract.* Each contract must be in writing and include the following information:

(1) Name of contractor.

(2) Services furnished (including work schedule if appropriate).

(3) Payment rate and method.

(4) Terms of the contract, including beginning and ending dates, methods of extension, renegotiation, and termination.

(5) Contractor agreement to do the following:

(i) Furnish only those services authorized by the PACE interdisciplinary team.

(ii) Accept payment from the PACE organization as payment in full, and not bill participants, CMS, the State administering agency, or private insurers.

(iii) Hold harmless CMS, the State, and PACE participants if the PACE organization does not pay for services performed by the contractor in accordance with the contract.

(iv) Not assign the contract or delegate duties under the contract unless it obtains prior written approval from the PACE organization.

(v) Submit reports required by the PACE organization.

(vi) Agree to perform all the duties related to its position as specified in this part.

(vii) Participate in interdisciplinary team meeting as required.

(viii) Agree to be accountable to the PACE organization.